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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,528	02/26/2004	Robert Portmann	4-30028C	6451

1095 7590 10/19/2004

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,528	PORTMANN ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a continuation of SN 10/294,408. A preliminary amendment was filed dated April 12, 2004. Claims 1-15 have been canceled. Claims 16-26 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheung et al. supplemented with structural delineation by CA.

Cheung et al. disclosed method of treating epilepsy (see p.1878 last paragraph) by oral administration (see p.1879 clinical procedure) the structure of the compound CGP33101 has been provided by CA abstract and to be identical to the claimed forms chemically.

Contrary to attorney' allegation that the instant claims are believed to be process involving the use of a novel and unobvious composition of matter, the instant claims are drawn to "method" of using new *forms* of an old product. Please note that the *chemical nature* of the instant claimed crystalline form A or A' are ***identical*** to the known compound CGP33101.

Applicants are well aware of that polymorphs are products having different "physical property" i.e. forms. The different forms i.e. polymorphs "can be patented if they can be shown to have better properties than others" (see Chem. Eng. News recited on 1449), thus, they are chemically identical products. While the different physical form when having unexpected property can merit patentability, such form have no merit on physiological application such as treatment of epilepsy. It is well known in the art that therapeutic method functions at physiological environment wherein an aqueous solution is the base of drug action. In aqueous phase, *all physical form is amorphous* (see Ulicky). Therefore, the method of using the instant *different form* is identical to the method of using any other form of the prior art since all forms become solution i.e. amorphous when treatment is employed.

It is noted that for a method of treatment to be different from each other one of the elements of the process including the drug, the site of administration, or the dosage of efficacy

must be differentiated (see Wyngaarden textbook of medicine p.48-55). In the instant case, it has been shown that the instantly claimed "form" would be innately amorphous thus would be identical "drug" as the prior art, the site of administration is oral and the dosage of efficacy based on disclosure of page 11 is between 50-500 mg, therefore, the 400 mg oral administration anticipated the instant claims.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness

Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung et al. in view of Chem. Eng. New (recited on 1449) supplemented with CA 108, 106, 105, 104, 101, 95, 94, 90, 80 (11 abstracts).

Determination of the scope and content of the prior art (MPEP §2141.01)

Cheung et al. disclosed method of treating epilepsy with the claimed compound by oral administration to man wherein a dosage operable for healthy subjects is 400mg.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claimed method, in view of the dosage disclosed on page 11, is that the dosage was between 20-500 mg while the prior art dosage is 400mg for which anticipation was found supra.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

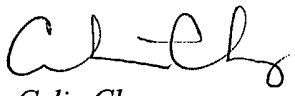
One having ordinary skill in the art would find the instant method prima facie obvious over the known method **because** it is well recognized in the art that polymorphs have different bioavailability which is expected to result in different dosage requirement in administration (see Chem. Eng. New recited on 1449, page 33, please note that the summary of the scientific knowledge in this article published in 2003 is based on prior art which abundantly disclosed this

factual summary, see CA abstracts attached). Therefore, the variation in dosage administration is "expected" for a different form. One skilled in the art in possession of Cheung et al. reference would expect to modify with variation of dosage used for the old form since this is an expected property prima facie obvious to one skilled in the art.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



OACS/Chang
Oct. 7, 2004

Celia Chang
Primary Examiner
Art Unit 1625